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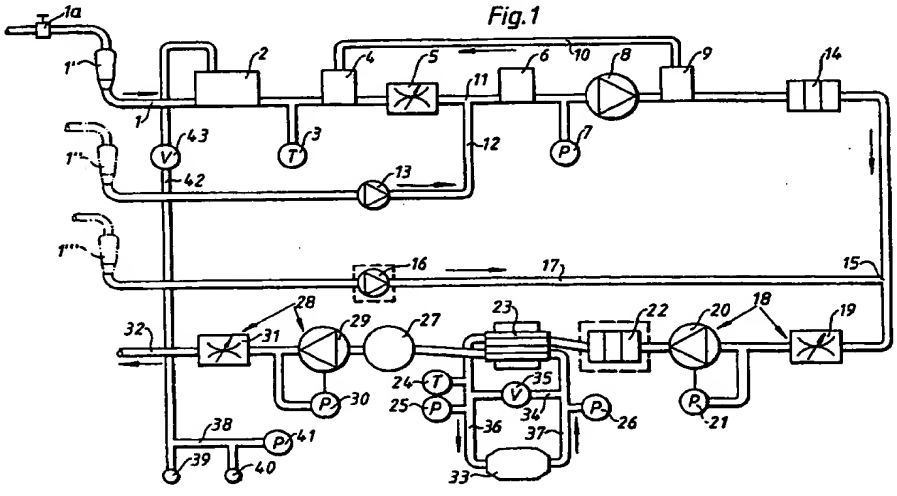
(54) System for controlling a medical treatment, for example dialysis.

(57) System for controlling a medical treatment, for example dialysis, using a preferably heated treatment fluid, comprising means (18,28) for controlling the flow of the fluid through the system and means (36,37) for connecting the system to a treatment device, for example a dialyzer (33), whereby disinfection and/or sterilization and/or other cleansing of the system is effected with the aid of a liquid which is made to flow along the same path as the treatment fluid, except that it is diverted past the treatment device by means of a so called by-pass arrangement (38-41 and/or 34,35).

The system according to the invention is characterized by means for connecting a cartridge or other vessel (1' ,1" or 1"') to a conduit (1,12,17) in the system, wherein the cartridge or vessel contains a soluble concentrate in liquid or powder form, preferably powder form, which achieves or at least aids the said cleansing, and by means (1a) for supplying water or another solvent to said conduit (1) to flow through and dissolve the concentrate.

Fig.1



EP 0 458 041 A1

TECHNICAL FIELD

The present invention relates to a system for controlling a medical treatment, for example dialysis, using a preferably heated treatment fluid, comprising means for controlling the flow of the fluid through the system and means for connecting the system to a treatment device, for example a dialyzer, whereby disinfection and/or sterilization and/or other cleansing of the system is effected with the aid of a liquid which is made to flow along the same path as the treatment fluid, except that it is diverted past the treatment device by means of a so called by-pass arrangement.

Preferably, the system according to the invention is intended for preparation of dialysis fluid in connection with haemodialysis. With minor modifications it can also, however, be used for preparation of replacement fluid in connection with haemofiltration or haemodiafiltration. It will be evident to the skilled man that the system can also be used in connection with many other treatment methods where a treatment fluid is utilized or such a fluid is produced, for example wound rinsing fluid.

BACKGROUND

A treatment fluid based on bicarbonate was originally used for dialysis. When the systems and monitors for this were later automated, difficulties arose, amongst them, precipitation. Other treatment fluids were therefore used instead, for example fluids based on acetate. Recently bicarbonate-based liquids have again found favour, at the same time the previously thought insurmountable problems have in the main been overcome. However, certain problems still remain with precipitation. Systems in use must thus be often cleansed at regular intervals. Hitherto this has been achieved by rinsing the systems with the aid of a cleansing liquid, for example citric acid.

American Patent 4 728 496 describes a system for disinfection and/or sterilization of, by way of example, a dialysis monitor. According to this system the fluid used for the treatment is recirculated within the parts which precede the dialyzer. As is explained in the following, this system can after a certain addition also be used for application of the present invention.

American Patent 4 784 495 describes another system for controlling a medical treatment, for example dialysis, wherein the utilized treatment fluid is prepared from a powder-based concentrate, for example sodium bicarbonate. Even in this system the present invention can be advantageously applied.

DESCRIPTION OF THE INVENTION

An object of the present invention is to accomplish in a simple manner cleansing of systems of the above-mentioned type. The system is characterized by means for connecting a cartridge or other vessel to a conduit in the system, wherein the cartridge or vessel contains a soluble concentrate in liquid or powder-form, preferably powder-form, which achieves or at least aids the said cleansing, and by means for supplying water or another solvent to said conduit to flow through and dissolve the concentrate.

Preferably, the system according to the invention includes means for recirculating at least a part of the fluid within at least a part of the system. This recirculation is, accordingly, suitably arranged to be effected with the aid of a particular return conduit from a location downstream in the system to a location at the start of the system in such a way as described, for example, in the above-mentioned American Patent 4 728 496.

The recirculation is suitably arranged to be effected from said by-pass arrangement, i.e. within the part of the system which normally contains one of the treatment device's unaffected treatment fluids.

Preferably no recirculation occurs in the part of the system which normally has treatment fluid flowing therethrough which has been affected by, and thus possibly contaminated by, the treatment device.

A preferred embodiment of this system according to the invention is characterized in that the system's normal heating device is arranged to increase the temperature in the fluid heating vessel during disinfection to, by way of example, a little over 90 °C and that recirculation is selected such that the temperature in the recirculation circuit does not drop substantially below the chosen temperature, whilst the temperature in the system after the recirculation location is allowed to gradually sink to a value of, for example, 80 °C. Thus, cleansing of the most important parts of the system, i.e. the parts preceding the dialyzer, is assured, whilst at the same time a satisfactory cleansing of the subsequent parts is achieved. Considerably lower temperatures can of course be also chosen, particularly if just cleaning is desired. The temperature is of course dependent upon which cleansing material is chosen.

The cleansing is suitably arranged to take place at substantially normal atmospheric pressure. In this way the dimensioning of the system is made easier and cheaper.

An effective cleansing is achieved if this is arranged to occur with substantially maximum flow in the recirculation circuit, whilst the flow in the

remainder of the system is arranged to be maintained at a fraction thereof, for example, one fifth thereof.

Throttles included in the recirculation circuit are, during cleansing, suitably arranged to be open and/or totally or partially by-passed to reduce flow resistance. In this way it is possible to guarantee that all the parts of the system are cleansed.

Likewise, if the preferably heated treatment fluid is arranged to be prepared by connecting a cartridge or another vessel comprising, for example, a powder-based concentrate, then the means for connecting the various cartridges can be identical. Such is the case for example if the invention is applied to the system according to the above-mentioned American Patent 4 784 495. The cartridge with cleansing concentrate can hereby be connected during cleansing, instead of the normally connected cartridge containing treatment concentrate. The system and its control means is programmed in such a way that treatment and cleansing cannot be confused.

The invention also comprises a cartridge or other vessel intended to be used in the above-mentioned system. The cartridge is characterized in that it contains precisely the quantity of concentrate necessary for cleansing with regard to the system's normal fluid volume and selected cleansing temperature.

To assure that the cleansing concentrate is not contaminated or in any way contacted with undesirable substances, the cartridge is produced completely sealed and is provided with penetrable membranes at its inlet and outlet.

Preferably the cartridge contains any one of the following concentrates: citric acid, acetic acid, peracetic acid, oxalic acid, sodium hydroxide, sodium hypochloride, sodium carbonate or suitable combinations thereof, though preferably citric acid. In practice it has shown to be suitable to use citric acid, this being in crystalline form. If a finer powder is used, then there is a risk of clogging of the cartridge.

BRIEF DESCRIPTION OF DRAWINGS

Figure 1 shows a block-diagram for a system designed according to the invention.

Figure 2 shows means for connecting a concentrate cartridge or other vessel to the system according to Figure 1.

BEST MODE FOR CARRYING OUT THE INVENTION

In the example of the system shown in the drawing, water is supplied via an inlet 1a through a water conduit 1 to a heating device 2 where it is heated. In the illustrated block diagram three various possible connection positions 1', 1" respectively 1"' are shown for the above-discussed cartridge or other vessel containing a cleansing concentrate. The same cartridge is shown in Figure 2 with reference 10f together with means for its connection.

Water is led from the heating device 2 with or without cleansing concentrate via a temperature measuring device 3, a return vessel 4, a throttle 5, a bubble-expansion chamber 6, a pressure measuring device 7 and a pump 8 to a ventilating chamber 9. A return conduit 10 leads from the ventilator chamber 9 back to the return vessel 4 for returning separated air or other gases together with a small quantity of fluid. A return to the heating vessel 2 could instead be provided, but this would, however, require the use of resistant material, since dialysis concentrate is normally supplied to the point 11 via conduit 12 with the help of the pump 13. This part of the system corresponds in the main with the system which is described by way of example in the American Patent 4 158 034 and 4 293 409. The function of the expansion chamber 6 is described in more detail in American Patent 4 536 201. Fluid is led from the ventilating chamber 9 via a conductivity measuring cell 14 to a further mixing point 15 where any additional concentrate is supplied with the aid of the pump 16 and a conduit 17. This is on the assumption that a so called two-component-based dialysis concentrate is to be used, for example of the type which is described in EP-B-0 022 922. Dialysis fluid is led from the mixing point 15 through a first constant flow device 18 comprising a throttle 19, a pump 20 and a pressure measuring device 21.

The pressure measured by the pressure measuring device 21 is used for controlling the pump 20 so that a desired constant flow is achieved. After the pump 20 the flow is led through a conductivity measurer 22 and ultra-filtration control 23 via a temperature measurer 24 and a pressure measurer 25 to a dialyzer 33. From there the flow is normally led via a pressure measurer 26, said ultra-filtration control 23 and a blood detector 27 to a further constant flow device 28 comprising a pump 29, a pressure measurer 30 and a throttle device 31. Finally, the dialysate is led to an outlet 32.

The construction and function of the ultra-filtration control is described in more detail in GB-B-2 003 274 and EP-B-0 106 940. Figure reference numeral 33 denotes the dialyzer connectable to the system according to the invention, to whose blood-side the patient is connected. This latter connection is, however, not shown in Figure 1.

The dialyzer 33 can be by-passed in two ways. This can occur either with the aid of by-pass con-

duit 34 with valve 35, which opens, for example if the temperature or the conductivity exceeds or falls below predetermined level. At the same time, the flow to the dialyzer is interrupted with the help of a not shown valve.

Alternatively, the by-pass can occur by means of the dialyzer connections 36 and 37 being connected to a by-pass conduit 38 via connections 39 and 40. This by-pass arrangement is principally designed according to American Patent 4 122 010 with a pressure monitoring device 41 which detects if a positive or negative pressure arises in conduit 38. If such is the case, and only then, sterilizing and/or cleansing can take place.

In the shown example a return conduit 42 with a valve 43 extends from the by-pass arrangement 38 back to the heating vessel 2. A quantity of the flow recirculates through this conduit 42 when the system is to be disinfected and/or sterilized and/or cleansed in any other way. The remainder of the flow is instead led from conduit 36 which is connected to connector 39 via conduit 38 and connector 40 to the conduit 37 and from there through the ultra-filtration control 23 and further to the outlet 32. A smaller quantity is, however, led directly from the conduit 36 via the conduit 34 with the valve 35 directly to the conduit 37 for cleansing of the by-pass connection.

According to the invention a cartridge or other vessel containing a cleansing concentrate is connected at 1', 1" or 1'". An example of such a connection is shown in Figure 2. The cartridge consists here of a closed vessel 10f which is provided at its ends with penetrable membranes 62 and 64.

The cartridge 10f and means for its connection to the system according to the invention can be designed totally in accordance with the above-mentioned American Patent 4 784 495. The difference is solely that the cartridge shall contain a cleansing concentrate instead of a treatment concentrate. The cartridge 10f is thus connected to the system with the aid of penetrating nippels 46 and 47 which are arranged on two lever arms 44 and 45. Fluid is supplied via nippel 46 and removed via nippel 47. The idea behind the lever arms 44 and 45 is that the system can also be used without a cartridge. The lever arms are swung to a position such that the nippels 46 and 47 are connected instead to a by-pass conduit connected to two nippels 48 and 49. These nippels, like the lever arms 44 and 45, are fixed to the wall 60 of a not shown control-monitor, for example such as used for controlling dialysis.

Examples of applicable cleansing agents can be: citric acid, acetic acid, peracetic acid, oxalic acid, sodium hydroxide, sodium hypochloride, sodium carbonates or suitable combinations thereof, though preferably citric acid. When citric acid is used, a suitable solution is obtained when 40 grams of citric acid is dissolved in two litres of water to a concentration of two per cent.

Alternatively, the citric acid can be "spiked" with oxalic acid. In this way any iron and copper precipitations are dissolved. By way of example a water solution can be used containing sixteen per cent citric acid and four per cent oxalic acid. This gives a very effective cleansing. A further alternative is the use of a water solution comprising 150 g/l sodium hypochloride, 4 g/l sodium hydroxide and 10-25 g/l of sodium carbonate which gives an effective cleansing after suitable dilution (approx. 20 times).

The above-mentioned solutions can be prepared in advance. Preferably, however, they are prepared directly in the system since the connected cartridge contains the concentrates in powder form.

Many advantages are obtained with the invention. In addition to the above-mentioned advantages, no mixing of the cleansing solution is needed in the clinic or pharmacy. Instead this can take place directly in the system. The possibility of using powder concentrate offers weight-saving advantages. However, not all concentrates need to be in powder form, since it is important that the invention can also be used with the aid of liquid-based concentrates.

The utilized concentrate cartridge can be connected at the beginning of the cleansing program and remain so during the whole of the rinsing program, which always follows the cleansing. This makes handling simpler. Cleansing agents which are harmless for the patient can be used. For example, citric acid is a basic food stuff and, as such, any small remnents are harmless for the patient. An important advantage is also the possibility to use various cleansing agents suited to respective treatment systems and conditions of use. The function of the system itself is also safer through effective cleansing. For dialysis, the necessary program change in existing programs is very slight.

Naturally, the invention is not restriced to the above described examples, but can be varied within the scope of the appended claims. For example, the shown details can be varied within wide limits of form and function.

Claims

1. System for controlling a medical treatment, for example dialysis, using a preferably heated treatment fluid, comprising means (18,28) for controlling the flow of the fluid through the system and means (36,37) for connecting the

system to a treatment device, for example a dialyzer (33), whereby disinfection and/or sterilization and/or other cleansing of the system is effected with the aid of a liquid which is made to flow along the same path as the treatment fluid, except that it is diverted past the treatment device by means of a so called by-pass arrangement (38-41 and/or 34-35), **characterized** by means (43) for connecting a cartridge or other vessel (1', 1" or 1"') to a conduit (1,12,17) in the system, wherein the cartridge or vessel contains a soluble concentrate in liquid or powder form, preferably powder form, which achieves or at least aids the said cleansing, and by means (1a) for supplying water or another solvent to said conduit (1) to flow through and dissolve the concentrate.

2. System according to claim 1, comprising means (42) for recirculating at least a part of the fluid within at least a part of the system, **characterized** in that said recirculation is arranged to be effected with the aid of a particular return conduit (42) from a location downstream in the system to a location at the start of the system.

3. System according to claim 2, **characterized** in that the recirculation is arranged to be effected from said by-pass arrangement (38-41), i.e. within the part of the system which normally contains one of the treatment device's (33) unaffected treatment fluids.

4. System according to claim 3, **characterized** in that no recirculation occurs in the part of the system which normally has treatment fluids flowing therethrough which has been affected by, and thus possibly contaminated by, the treatment device (33).

5. System according to any one of the preceeding claims, **characterized** in that the system's normal heating device (2) is arranged to increase the temperature in the fluid heating vessel during disinfection to, by way of example, a little over 90° C and that recirculation is selected such that the temperature in the recirculation circuit does not drop substanially below the chosen temperature, whilst the temperature in the system after the recirculation location is allowed to gradually sink to a value of, for example, 80° C.

6. System according to any one of the preceeding claims, **characterized** in that cleansing is arranged to take place at substantially normal atmospheric pressure.

7. System according to any one of the preceeding claims, **characterized** in that cleansing is arranged to occur with substantially maximum flow in the recirculation circuit, whilst the flow in the remainder of the system is arranged to be maintained at a fraction thereof, for example, one fifth thereof.

8. System according to any one of the preceeding claims, **characterized** in that throttles included in the recirculation circuit are, during cleansing, arranged to be open and/or totally or partially by-passed to reduce flow-resistance.

9. System according to any one of the preceeding claims, whereby the preferably heated treatment fluid is arranged to be prepared by connecting a cartridge or another vessel containing a powder-based concentrate, **characterized** in that means for connecting the various cartridges are identical.

10. Cartridge or other vessel intended to be used in a system according to any of claims 1-9, **characterized** in that it contains precisely the quantity of concentrate necessary for cleansing with regard to the system's normal fluid volume and selected cleansing temperature.

11. Cartridge or other vessel according to claim 10, **characterized** in that it is completely sealed and is provided with penetrable membranes at its inlet and outlet.

12. Cartridge or other vessel according to any one of claims 10 and 11, **characterized** in that it contains any one of the following concentrates: citric acid, peracetic acid, oxalic acid, sodium hydroxide, sodium hypochloride, sodium carbonate or suitable combinations thereof, though preferably citric acid.

13. Cartridge or other vessel according to any one of claims 10-12, **characterized** in that the concentrate is powder-based and is preferably citric acid in crystalline form.

Fig.1

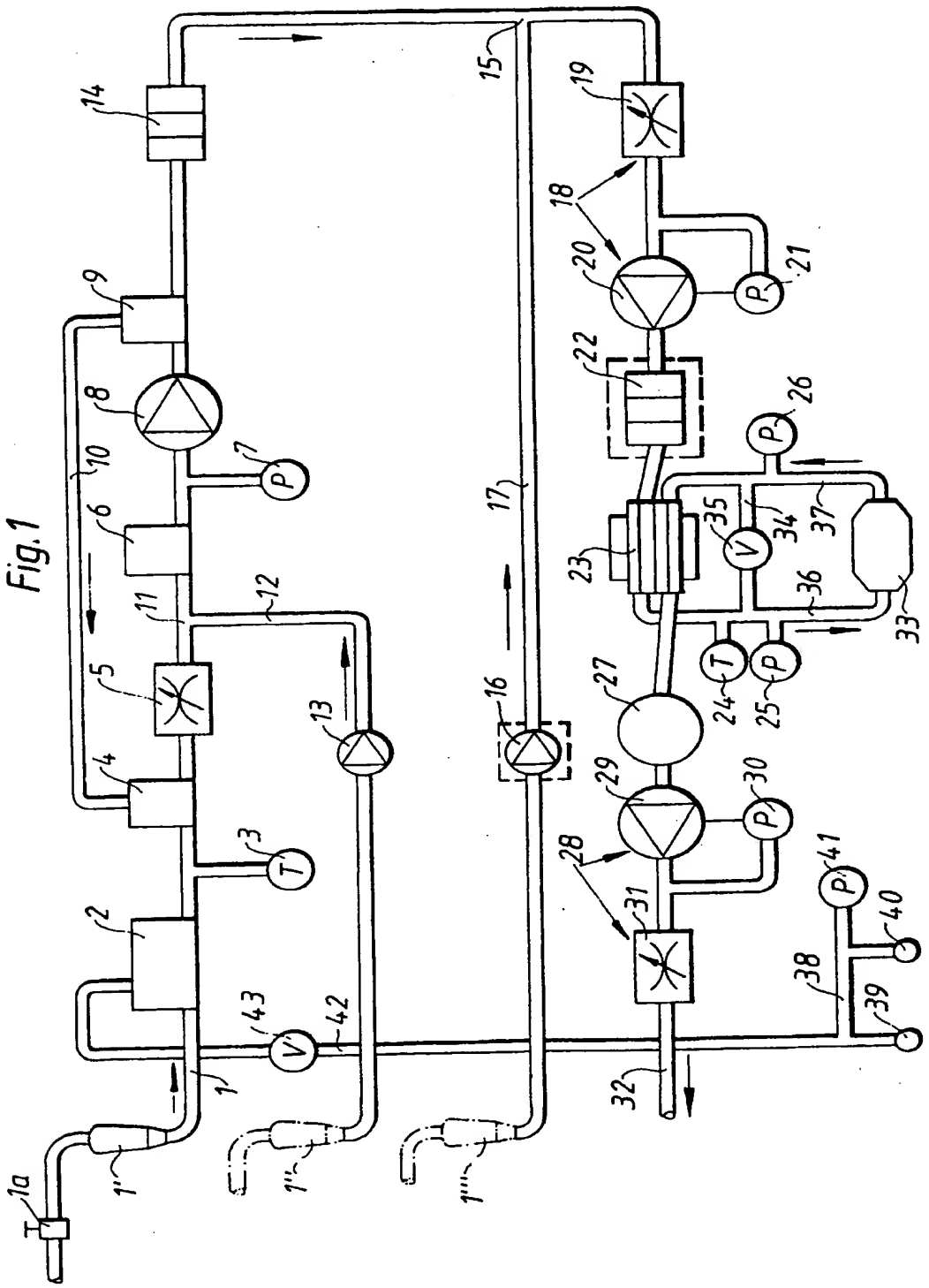

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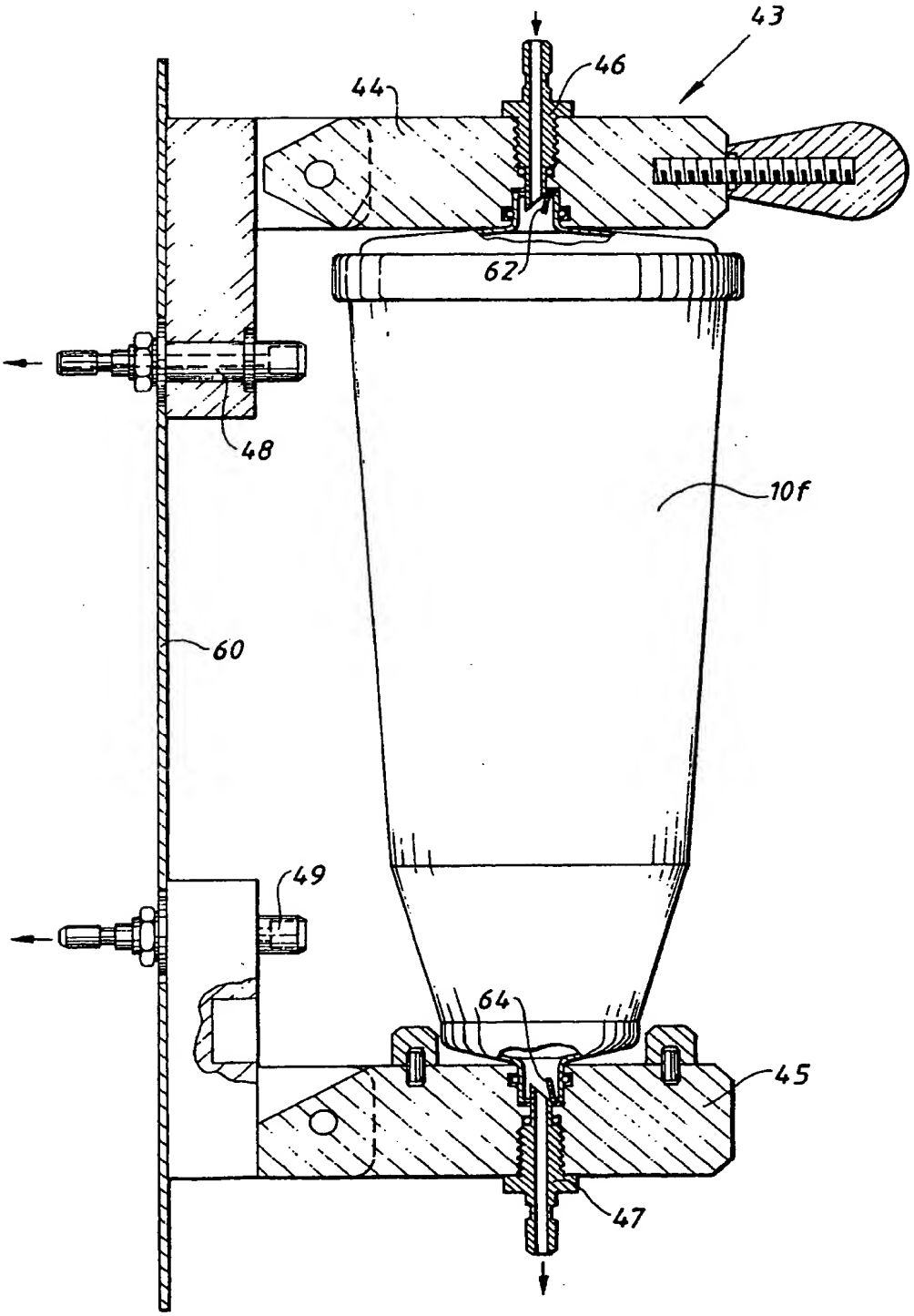
Fig.2



European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 91105180.3

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
D,Y	US - A - 4 728 496 (P.A. PETERSON et al.) * Totality * --	1-8	A 61 M 1/14
Y	US - A - 4 789 467 (E.R. LINDSAY et al.) * Totality; especially fig. 1-3; column 5, lines 4-68; column 10, line 39 - column 11, line 60; column 12, lines 33-53; column 13, lines 28-31; column 14, lines 11-16 *	1-8	
A		10	
	--		
D,A	US - A - 4 784 495 (L.U.P. JONSSON et al.) * Totality; especially fig. 6-8; column 9, line 30 - column 17, line 12 * --	1,9-13	
D,A	US - A - 4 158 034 (G. RIEDE et al.) * Fig.; column 3, lines 1-15 * --	1	TECHNICAL FIELDS SEARCHED (Int. Cl.5) A 61 M
A	GB - A - 1 368 518 (DIALYSIS SYSTEMS) * Totality; especially page 2, lines 25-36 * ----	1	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
VIENNA	10-09-1991	LUDWIG

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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